Reporting guideline for the early stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI

Abstract

A growing number of artificial intelligence (AI)-based clinical decision support systems are showing promising performance in preclinical, in silico, evaluation, but few have yet demonstrated real benefit to patient care. Early stage clinical evaluation is important to assess an AI system's actual clinical performance at small scale, ensure its safety, evaluate the human factors surrounding its use, and pave the way to further large scale trials. However, the reporting of these early studies remains inadequate. The present statement provides a multistakeholder, consensus-based reporting guideline for the Developmental and Exploratory Clinical Investigations of DEcision support systems driven by Artificial Intelligence (DECIDE-AI). We conducted a two round, modified Delphi process to collect and analyse expert opinion on the reporting of early clinical evaluation of AI systems. Experts were recruited from 20 predefined stakeholder categories. The final composition and wording of the guideline was determined at a virtual consensus meeting. The checklist and the Explanation & Elaboration (E&E) sections were refined based on feedback from a qualitative evaluation process. 123 experts participated in the first round of Delphi, 138 in the second, 16 in the consensus meeting, and 16 in the qualitative evaluation. The DECIDE-AI reporting guideline comprises 17 AI specific reporting items (made of 28 subitems) and 10 generic reporting items, with an E&E paragraph provided for each. Through consultation and consensus with a range of stakeholders, we have developed a guideline comprising key items that should be reported in early stage clinical studies of AI-based decision support systems in healthcare. By providing an actionable checklist of minimal reporting items, the DECIDE-AI guideline will facilitate the appraisal of these studies and replicability of their findings.